REMARKS/ARGUMENTS

I. Claim Rejections under 35 U.S.C. § 112

The Final Office Action, dated February 11, 2002, maintains its rejection of claims 22-26 under 35 U.S.C. 112, first paragraph. The Final Office Action asserts that it would have required undue experimentation for one skilled in the art to expect that the sperm-specific antibodies of the present invention would retain the ability to fertilize an oocyte. In particular, the Final Office Action premises its rejections on articles in the art of immunocentraception which show certain antibodies bound to the surface of sperm cells inhibit fertilization. *See* Yan *et al.*, Nakamura *et al*, Naz *et al.*, Kim *et al.*, also cited in a prior Office Action dated 28 August 2002. The Final Office Action quotes a statement from Nakamura *et al* teaching that "it is believed that antisperm antibodies cause infertility in some male and female patients". The Final Office Action then concludes that "in general antibodies directed to sperm would be expected to inhibit fertilization".

The Interview Summary, dated April 30, 2003, reflects a telephonic interview conducted on April 24, 2003, among Applicant, Examiner Thai-An Ton and Examiner Deborah Crouch. During the interview, Examiners asked whether Applicant had an additional antibody other than mAbC that possesses the features of the claimed antibody. When Applicant provided a positive response, Examiners advised that a 37 C.F.R. 1.132 Affidavit may be used to overcome the rejections of claims 22-26 under 35 U.S.C. 112, first paragraph. Examiners further advised that the Affidavit should show that the additional antibody has been made using the same method in the specification and will bind to a sperm cell, retain the sperm cell's ability to fertilize an oocyte, and carry DNA into the oocyte from which a transgenic offspring will develop.

Pursuant to the above advice, Applicant hereby submits a 37 C.F.R. 1.132 Affidavit showing that more than one antibody has been made according to methods taught in the specification. In particular, Applicant has shown that antibodies 1B3(1A8), 2D4 (1F3), 3C7(2C5), 2E8(2G5), 4E7(1F11), and 1F5(1D8), which are made according to the method disclosed in the specification, have binding affinity to sperm cells which

when bound with the antibodies retain the ability to fertilize oocytes. In addition, more than one antibody (mAbC and mAbD) has demonstrated that sperm cells bound with the antibody are able to carry transgene DNA and fertilize an oocyte from which a transgenic animal develops and contains the transgene.

Applicant further notes that the present invention is in parallel with In re Wands, 858 F.2d 731 (1988). In Wands, the claimed invention was directed to a method for immunoassay of HBsAg by using high-affinity monoclonal IgM antibodies. 858 F.2d at 734. Prior to Wands, most immunoassays used IgG isotype. IgM were disfavored because of their sensitivity to reducing agents and their tendency to self-aggregate and precipitate. Id. The position of the PTO was that the production of high-affinity IgM anti-HbsAg antibodies was unpredictable and unreliable, and therefore, the PTO asserted that it would require undue experimentation to make the antibodies. 858 F.2d at 735. The Federal Circuit Court reversed the PTO's rejection of Wands' claims as not enabling. The Court ruled that undue experimentation would not be required to practice the invention when the "disclosure provides considerable direction and guidance on how to practice their invention and presents working examples" and there is "high level of skill in the art at the time the application was filed" and "all of the methods needed to practice the invention were well known". 858 F.2d at 740. Furthermore, "it seems unlikely that undue experimentation would be defined in terms of the number of" experiments. Id. A considerable amount of experimentation is permissible, if it is merely routine. 858 F.2d at 737.

The present application is a continuation-in-part of Application No. 09/537,861 (the '861 Application). In the `861 Application, Applicant provides considerable direction and guidance in making and screening sperm-specific antibodies. The procedure entails immunizing mice with mouse sperm cells and screening sperm-binding antibodies with flow cytometry (See Example I of the `861 Application). Applicant also teaches that, to determine whether the sperm binding antibodies would not inhibit fertilization, sperm cells bound with the antibodies may be incubated with oocytes and resulting zygotes may then be cultured into blastocytes which are readily observable. (Example III of the present application). It is common knowledge that if the

fertilization is inhibited no blastocyte will be formed or observed. Moreover, Applicant teaches to perform a Southern blot analysis to confirm the integration of DNA into the genome of a transgenic animal (Example IV of the `861 Application).

Put together, Applicant provides considerable direction and guidance on how to practice claimed invention by making antibodies that bind to a sperm cell and retain the sperm cell's ability to fertilize an oocyte. Applicant also provides guidance as to whether a sperm cell bound with a DNA-associated antibody will introduce the DNA into an oocyte upon fertilization.

Furthermore, Applicant presents a working example, mAbC, in the specification. Applicant has also made a number of antibodies having the properties in the claimed invention in the 37 C.F.R. 1.132 Affidavit submitted herein.

Finally, Applicant notes that all the methods to practice claimed invention are well known and routine in the art.

In light of the foregoing discussion, given further that Applicant has submitted a 37 C.F.R. 1.132 Affidavit, Applicant concludes that it would not require undue experimentation to make and/or use the claimed antibodies, much less to expect that the claimed antibodies would retain the ability to fertilize an oocyte. Accordingly, Applicant respectfully requests that the rejections of claims 22-26 be reconsidered and withdrawn.

II. Deposit of Biological Materials

The Final Office Action asserts that the Written Assurance pursuant to 37 C.F.R. 1.809, submitted by Applicant on November 27, 2002, is not clear.

During the telephonic interview conducted on April 24, 2003, Applicant was advised that if the rejections under 35 U.S.C. 112 are overcome the deposit of biological materials is not required.

As discussed in the Section (I) of this paper, Applicant has submitted a 37 C.F.R. 1.132 Affidavit and concluded that it would not require undue experimentation to make and/or use the claimed antibodies. Since the rejections under 35 U.S.C. 112 are overcome, Applicant believes that the deposit of biological materials is not required under 37 C.F.R. 1.802.

In view of the foregoing, the claims 22-26 are in condition for allowance. Therefore, a Notice of Allowance is respectfully requested.

Respectfully submitted,

Perkins Coie LLP

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James J. Zhu, Ph.D.
Registration No.52,396

Correspondence Address:
Customer No. 34055
Perkins Coie LLP
P.O.Box 1208
Seattle, WA 98111-1208
Telephone: (310) 788-9900
Facsimile: (310) 788-3399